PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 25/00, 39/12, F16L 31/00, B29C 65/68 — A1

(11) International Publication Number: **WO 98/22175**

(43) International Publication Date: 28 May 1998 (28.05.98)

(21) International Application Number: PCT/US97/21693

(22) International Filing Date: 20 November 1997 (20.11.97)

(30) Priority Data:

60/031,344	21 November 1996 (21.11.96)	US
Not furnished	17 November 1997 (17.11.97)	US

(71)(72) Applicants and Inventors: SACHDEVA, Rohit, C., L. [US/US]; 2605 Courtside Lane, Plano, TX 75093 (US). BESSELINK, Petrus, A. [NL/NL]; Gronausestraat 1220, NL–7534 AT Enschede (NL). VAN DEN HOUT, Fritz [NL/NL]; P.P. Rubenspad 25, NL–5062 KL Oisterwijk (NL). DE BOER, Henk, C. [NL/NL]; NL–5554 RC Valkenswaard (NL).

(74) Agents: AHRENS, Gregory, F. et al.; Wood, Herron & Evans, L.L.P., 2700 Carew Tower, Cincinnati, OH 45202 (US).

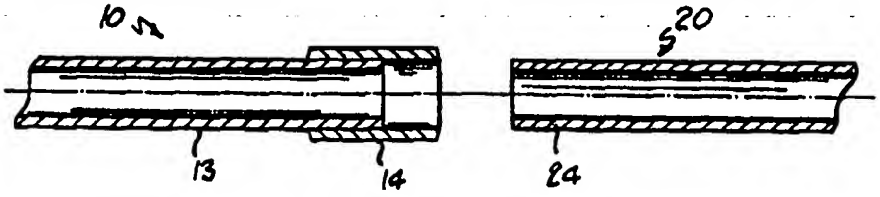
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: MODULAR BALLOON CATHETER



(57) Abstract

A modular balloon catheter is provided with proximal (10) and distal (20) shafts which can be coupled by a connector (14) made from a shape memory alloy. The proximal shaft (10) of the catheter can be connected to the fluid supply source by either a conventional connector or a connector which is designed for and is made of a shape memory material.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

MODULAR BALLOON CATHETER

Related Applications

Pursuant to 37 C.F.R. §1.78(a)(4), this application is a continuation of, claims the benefit of and priority to prior filed co-pending Provisional Application Number 60/031,344, filed November 21, 1996, which is expressly incorporated herein by reference.

Field of the Invention

The invention relates generally to modular balloon catheter, and more particularly to a modular balloon catheter which incorporates one or more connectors made from a shape memory material.

Balloon catheters have been used by the medical community for years to expand vessels which are constricted by plaque buildups. Traditional balloon catheters are constructed of a long tube or hollow shaft with a hub connector at the proximal end of the tube and an expandable balloon and tip at or near the distal end of the tube. Fig. 1 shows one such hub connector manufactured by Occam International BV. A supply line, which is used to provide fluid to inflate or expand the balloon, attaches to the hub connector. In one traditional use for such catheters, known as percutaneous transluminal

coronary angioplasty, the catheter with the balloon in a deflated state is inserted through an incision made through the patient's skin, subdermal tissue, and side wall of a vessel. The catheter is then directed through various interconnecting vessels to the constricted area of interest. Once in place, the fluid pressure is increased to expand the balloon to the desired size, then reduced to deflate the balloon. This cycle of increasing fluid pressure to expand the balloon then decreasing fluid pressure to deflate the balloon may be repeated a number of times to achieve the desired expansion effect on the vessel being treated. After the treatment has been completed, the catheter is removed from the patient's body while the balloon is in a deflated state.

Often it is advantageous to use catheters equipped with balloons of varying size, length, etc. to perform a procedure. Changes between different balloon configuration must be accomplished quickly and easily since the patient is normally under minimal sedation and may be experiencing the added stress of having experienced one or more episodes of cardiac dysfunction. These changes are accomplished by reducing the pressure of the expanding fluid to at or near ambient pressure and replacing the undesired balloon catheter with a balloon catheter of the desired configuration. As previously stated, traditional balloon catheters connect to the fluid supply line via a hub. The connection between the fluid supply line and the catheter is accomplished by a twist-locking motion which is cumbersome and often results in delays during the procedure.

Pressures used to expand a balloon during a medical procedure often reaches 20 Bar or higher. As a result, the connection between the fluid supply line and the catheter must be designed in such a way to accommodate

these levels of pressure while maintaining a connection that is free of leaks. In addition, axial, perpendicular, and rotational forces are imposed on the connection while a procedure is being conducted in a patient's body. The connection must be able to withstand these forces as well without leaking. The design of the connection must also take into account the small diameter of most vessels which requires that the connection mechanism also be very small.

Most balloon catheters are single use items; they are used on one patient during one procedure then discarded. A more cost effective and efficient approach would be to provide a catheter with a reusable proximal shaft attached to a small, single use, distal shaft, balloon, and tip assembly.

Traditional balloon catheters can be limited to their use due to their lack of flexibility, insufficient stiffness during positioning, and minimal resistance to kinking. These factors play a major role in determining the possible applications for these types of catheters.

Therefore, there is a need for a modular balloon catheter in which various balloon configurations can be readily interchanged by switching various single-use distal shafts in a reusable proximal shaft and the balloon can be pressurized without leakage at fluid connections which are small enough to pass through the inside dimension of small vessels.

One object of the invention is a modular balloon catheter.

Another object is a modular balloon catheter in which various balloon configurations can be readily interchanged.

A further object of the invention is a modular balloon catheter in which the catheter is comprised of a reusable proximal shaft and a single-use distal shaft incorporating a balloon.

Still another object is a modular balloon catheter in which the fluid line connections are small enough to pass within the inside dimension of small vessels.

Yet another object of the invention is a modular balloon catheter in which the fluid line connections provide a seal without leakage.

Additional objects, advantages, and novel features of the invention will be set forth in part in the description which follows, and in part will become apparent to those skilled in the art upon examination of the following or may be learned by practice of the invention.

Summary of the Invention

According to the present invention, the foregoing and other objects are attained by a modular balloon catheter with proximal and distal shafts which can be occupied by a connector made from a shape memory alloy. The proximal shaft of the catheter can be connected to the fluid supply source by either a conventional connector or a connector which is designed for and is made of a shape memory material.

Shape memory materials have several characteristics which make them particularly advantageous for this type of device. These materials exhibit different crystalline structures, and therefore varying physical properties, depending upon the temperature of the component made from a shape memory material. The crystalline structure changes configuration over a range of

temperatures, known as the material's transformation temperature range (TTR). Shape memory materials are generally weak and pliable when the material is at a temperature below its TTR and relatively strong with superelastic properties when the material is at a temperature above its TTR. Generally, the strength and superelastic characteristics tend to increase toward the higher temperature end of the material's TTR and decrease toward the lower end of its TTR. The characteristics of shape memory materials are well documented. For example, the book entitled Engineering Aspects of Shape Memory Alloys, published in 1990 by Butterworth and Heinemann and edited by T.W. Duerig, K.N. Melton, D. Stockel, and C.M. Wayman (ISBM No. 0-750-61009-3) is an excellent treatise on shape memory materials. Two articles therein, each of which are incorporated by reference herein in their entirety, entitled "An Introduction to Martensite and Shape Memory" by C.M. Wayman and T.W. Duerig, pages 3-20, and "The Mechanical Aspects of Constrained Recovery" by J.L. Proft and T.W. Duerig, pages 115-129, provide a good description of the issues surrounding shape memory materials. The unique properties of shape memory materials enable any structure made of such a material to have one geometric configuration or shape at a temperature below its TTR and another geometric configuration at a temperature above its TTR.

For purposes of the present invention, the working temperature of the catheter is typically a range of temperatures above the material's TTR, preferably those temperatures which would be encountered by the catheter during a medical or surgical procedure. Within these higher temperatures, connectors made from such a shape memory material are relatively strong with

superelastic properties. In addition, the shape of the connector while in this higher temperature range prevents the connector parts from being removed or disconnected from one another. In order to disconnect the connector, the temperature of the connector is lowered to a range of temperatures below the material's TTR. Within these lower temperatures, connectors made from such a shape memory material are generally weaker and more pliable than when the material is within a temperature range above its TTR. The shape of the connector while in this lower temperature range allows the connector parts to be removed or disconnected from each other freely. Connectors of this type can be used to join the proximal and distal portions of the catheter to join the fluid supply line to the proximal portion of the catheter.

Brief Description of the Drawings

Fig. 1 is a plan view of a traditional hub connector.

Fig. 2 is a sectional view of one embodiment of the present invention showing a proximal and a distal shaft prepared for insertion of the proximal end of the distal shaft into the distal end of the proximal shaft.

Fig. 3 is a sectional view of another embodiment of the present invention showing a proximal and a distal shaft prepared for insertion of the proximal end of the distal shaft into the distal end of the proximal shaft.

Fig. 4 is a sectional view of another embodiment of the present invention showing a proximal and a distal shaft prepared for insertion of the distal end of the proximal shaft into the proximal end of the distal shaft.

Fig. 5 is a sectional view of another embodiment of the present invention showing a proximal and a distal shaft prepared for insertion of the proximal end of the distal shaft into the distal end of the proximal shaft.

In one embodiment of the present invention, the proximal shaft can be made entirely in the shape of a long, cylindrical tube of superelastic shape memory material. This embodiment combines the advantages of enhanced flexibility, pushability, torqueability, and kinking resistance of a superelastic material with the benefits of a temperature sensitive connector. In this embodiment, the material has superelastic behavior at working temperature, but by cooling the tube to a temperature below the material's TTR, the material changes crystalline structure and becomes deformable.

Before the characteristics of shape memory materials can be used to create a mechanical connection between the proximal shaft and the distal shaft, the components must be trained to have the shapes desired. If the leading edge of the proximal tube is cooled, it will be possible to radially expand this tube temporarily by inserting a pin or tube with an outer diameter that is a maximum 8% larger than the inner diameter of the superelastic tube. As soon as the superelastic tube is warmed to ambient temperature, it will try to transform back to the high temperature phase. Before warming up, the proximal end of the distal shaft is put into the expanded section of the proximal shaft. The outer diameter of the proximal end of the distal shaft has a value that is larger than the inner diameter to which the tube would return if this recovery was not prevented. The recovery stress that builds up when warming up causes radial contraction, which is sufficient to produce a stable, leak free connection.

In accordance with another aspect of the invention, of course, the proximal shaft can be made of any acceptable material, such as, but not limited to, stainless steel. The connector can be used in the shape of a short piece of superelastic tube that clamps identically as in the previous case. Here, the superelastic tube clamps on two inserted parts: the distal end of the proximal shaft and the proximal end of the distal shaft. They are inserted with low force into the cooled connector tube and will be stable and leak free connected at ambient temperature. An alternative option with a short temperature sensitive tubular connector would be the use of a tube that is inserted permanently in the distal end of the proximal shaft and which can be compressed after cooling to enable the proximal end of the distal shaft to be slipped over the temporarily smaller diameter of the connector. During warming, the connector will radially expand and lock itself firmly into the distal shaft.

In accordance with yet another aspect of the invention, an external temperature variable locking ring can be used to clamp two telescopically engaged elements. If, for example, the proximal end of the distal shaft fits into the distal end of the proximal shaft over a certain insertion depth, it is possible to make a tight connection by elastic deformation of the outer part against a relatively rigid inner part by means of a variable locking ring. This locking ring can be cooled to loosen the compression force between the two connected parts, thus enabling the disconnection. In this embodiment, the most expensive parts of the construction are built in the reusable proximal shaft, which means that the temperature sensitive connector is placed at the distal end of the proximal shaft. Of course, the option is available to connect the proximal

end of the proximal shaft by means of the same principle to a hub that is used as a regular standard connector for medical practice.

The scope of the invention also encompasses the use of temperature sensitive connectors permanently attached at the proximal end of the distal shaft instead of the distal end of the proximal shaft. The temperature sensitive connector may be provided with an internal or external liner that can have several functions. The first function can be the improvement of sealing against leaking and the second can be the function of a biasing force. Such a biasing force can help to make the disconnection during cooling easier. An example is a heat shrinkable connector with an inner liner that can be elastically deformed by the shape memory material when it is in the warm condition. However, during cooling the shape memory material will loosen its contraction force, while the elastic expansion force of the liner remains constant. With proper tuning of the strength of both materials, it is possible to make a combined connector that opens during cooling and contracts during warming. If needed, the liner may have a pattern of slots to increase elasticity. For connectors that are heat expandable. it may be necessary to put the biasing liner around the shape memory material.

In Figs. 2-5, the distal end of a proximal shaft 10 can be mounted to the proximal end of a distal shaft 20 of the catheter by means of a temperature sensitive shape memory material.

Referring now to Fig. 2, shown is a superelastic tube 11 which has a leading end 12 that can be radially expanded after cooling below the TTR. The distal shaft 20 is made of a polymer or metallic part 21 which is

permanently connected to a metal insert ring 23 with its proximal end 22. After cooling, insert 23 can be put into section 12 and the temperature can be raised again to start the radial contraction of section 12 around insert 23. If needed, section 12 can be cooled, e.g., by ice water or any other suitable coolant, to enable the disconnection of the proximal 10 and distal 20 shafts. As can be readily seen, the internal diameters can be chosen in such a way as the fluid transfer through the catheter is not obstructed. Therefore, the connector part 12 of the superelastic tube 11 can be expanded and heat treated to produce the shape shown.

Referring now to Fig. 3, this embodiment is shown which reduces the amount of relatively expensive shape memory material required. Only the connector part 14 is made of shape memory material. The proximal shaft 10 is merely made of a conventional tube 13 welded to the connector 14. The insert 24 of the distal shaft 20 is pushed into the cold connector and then recovery during warming begins. The connector 14 may be provided with a biasing elastic liner (not shown) to enable a larger radial expansion during cooling, so that the insertion of the proximal end of the distal shaft requires less force to insert. This liner may have a pattern of slots to increase elasticity (not shown). An example of a slotted biasing element will be described in Fig. 5.

Referring now to Fig. 4, the use of a short, temperature sensitive connector 16 is shown. In the leading end of tube 15 of proximal shaft 10, a short length of connector 16 is permanently attached and the remaining length can be compressed during cooling. Now, the proximal end of insert 24 of distal

shaft 20 is brought over the connector 16 and recovery can begin, providing the connection.

Referring now to Fig. 5, a construction is provided where the proximal end 26 of the distal shaft 20 fits into the distal end of the proximal tube 17. The end of tube 17 is provided with slots 19 to enlarge the elasticity of the wall of tube 17. The end of proximal shaft 10 is surrounded by a ring 18 of a heat sensitive shape memory material. Insert and distal shaft are connected permanently. The wall of the distal shaft can be made of a polymer that may be elastic to achieve a proper recovery stress in ring 18 during warming. Therefore, the insert, with a higher stiffness than wall 25 may be necessary. The free end 26 of the insert can be put into the connector until it touches stop 27. The means that end 26 of the insert is placed deep enough to prevent leakage between the slots 19 and insert 26. Therefore, part 26 is longer than slots 19. Wall 25 can be permanently attached to part 28 of the insert using the same stop 27. The slotted section 19 can also be part of a separate biasing liner, as described in Fig. 2.

A further embodiment would be the use of more than one connector to interconnect more than two modular components of a balloon catheter system.

The temperature sensitive shape memory materials described herein can be a shape memory metal or a shape memory polymer, as well as a heat shrinkable thermoplastic.

Reasonable variations and modifications of the invention are possible within the scope of the foregoing disclosure of the invention. For example, although several embodiments of the invention have been illustrated in

the accompanying drawings and described in the foregoing best mode for carrying out the invention, the invention is not limited to the embodiments disclosed, but is capable of numerous rearrangements, modifications, and substitution of parts and elements without departing from the scope and spirit of the invention.

Claims - 13 -

1. A medical device, comprising:

a first catheter section;

a second catheter section; and

a ring-shaped connecting member for releasably coupling said first and second catheter sections, said connecting member made of a shape memory material which is operative for coupling and uncoupling said catheter sections upon passing through its transformation temperature range.

2. A medical device of claim 1 wherein said connecting member is sized and configured to encircle said first and second catheter sections.

3. A medical device of claim 2 wherein said connecting member contracts upon heating above its transformation temperature range to couple said first and second catheter sections.

4. A medical device of claim 3 wherein said connecting member loosens its contraction force upon cooling below its transformation temperature range to uncouple said first and second catheter sections.

5. A medical device of claim 2 wherein said connecting member contracts upon cooling below its transformation temperature range to couple said first and second catheter sections.

6. A medical device of claim 5 wherein said connecting member expands upon heating above its transformation temperature range to uncouple said first and second catheter sections.

7. A medical device of claim 2 wherein said connecting member is permanently attached to one of said first and second catheter sections.

8. A medical device of claim 7 wherein said connecting member is welded to one of said first and second catheter sections.

9. A medical device of claim 2 wherein said first catheter section has distal and proximal ends, said second catheter section has distal and proximal ends, and said distal end of said first catheter and said proximal end of said second catheter are telescopically engaged one within the other.

10. A medical device of claim 9 wherein said connecting member couples said telescopically engaged first and second catheter sections by compressing the outer catheter section against the inner catheter section.

11. A medical device of claim 10 wherein said outer catheter section is slotted to facilitate compression thereof.

12. A medical device of claim 1 wherein said connecting member is sized and configured to fit within said first and second catheter sections.

13. A medical device of claim 12 wherein said connecting member expands upon heating above its transformation temperature range to couple said first and second catheter sections.

14. A medical device of claim 13 wherein said connecting member contracts upon cooling below its transformation temperature range to uncouple said first and second catheter sections.

15. A medical device of claim 12 wherein said connecting member loosens its contraction force upon cooling below its transformation temperature range to couple said first and second catheter sections.

16. A medical device of claim 15 wherein said connecting member contracts upon heating above its transformation temperature range to uncouple said first and second catheter sections.

17. A medical device of claim 12 wherein said connecting member is permanently attached to one of said first and second catheter sections.

18. A medical device of claim 17 wherein said connecting member is welded to one of said first and second catheter sections.

19. A medical device of claim 1 wherein one of said first and second catheter sections is connected to a balloon catheter.

20. A medical device of claim 19 wherein the other of said first and second catheter sections is connected to a fluid supply source for inflating said balloon catheter.

21. A medical device of claim 1 wherein said shape memory material is selected from the group consisting of shape memory metals, shape memory polymers, and heat shrinkable thermoplastics.

22. A medical device of claim 1 further comprising a metal insert ring coupled to one of said first and second catheter sections and sized and configured to be releasably engaged by said ring-shaped connecting member to couple said first and second catheter sections.

23. A medical device comprising:

a first catheter section having proximal and distal ends;

a second catheter section having proximal and distal ends;

one of said first and second catheter sections being made of a shape memory material and said proximal end thereof sized and configured for releasably coupling with said distal end of the other of said first and second catheter sections upon passing through its transformation temperature range.

24. A medical device of claim 23 wherein said shape memory catheter section telescopically engages the other catheter section by encircling at least a portion thereof.

25. A medical device of claim 24 wherein said shape memory catheter section contracts upon heating above its transformation temperature range to couple said first and second catheter sections.

26. A medical device of claim 25 wherein said shape memory catheter section loosens its contraction force upon cooling below its transformation temperature range to uncouple said first and second catheter sections.

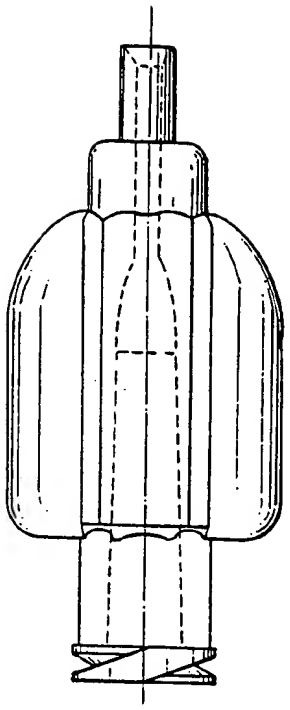
27. A medical device of claim 24 wherein said shape memory catheter section contracts upon cooling below its transformation temperature range to couple said first and second catheter sections.

28. A medical device of claim 27 wherein said shape memory catheter section expands upon heating above its transformation temperature range to uncouple said first and second catheter sections.

29. A medical device of claim 23 wherein one of said first and second catheter sections is connected to a balloon catheter.

30. A medical device of claim 29 wherein the other of said first and second catheter sections is connected to a fluid supply source for inflating said balloon catheter.

31. A medical device of claim 23 further comprising a metal insert ring coupled to the other of said first and second catheter sections and sized and configured to be releasably engaged by said one of said first and second catheter sections made of a shape memory material.



PRIOR ART

FIG.1

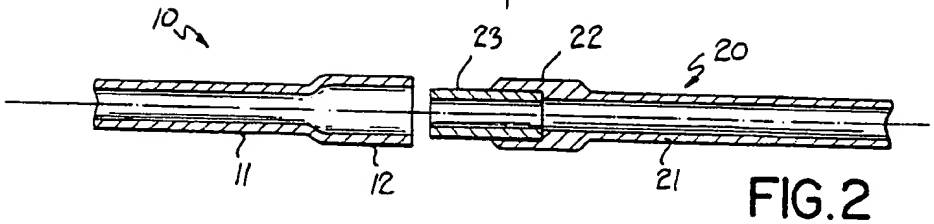


FIG.2

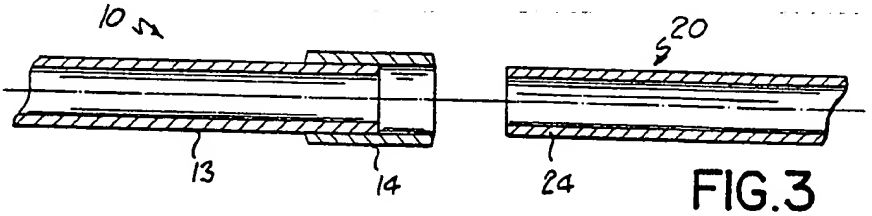


FIG.3

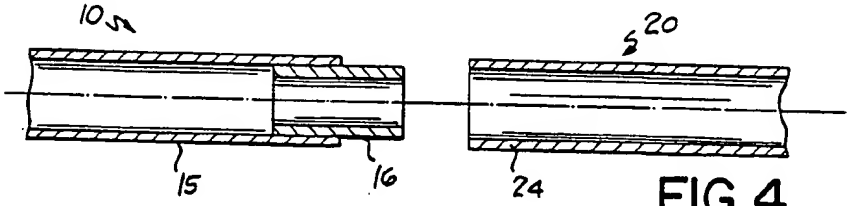


FIG.4

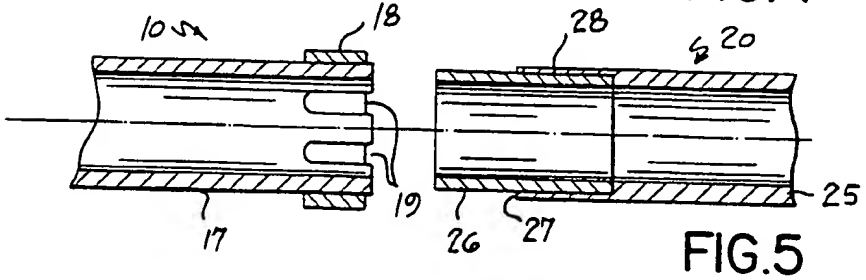


FIG.5

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/US 97/21693

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/00 A61M39/12 F16L31/00 B29C65/68

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M F16L B29C

Documentation searched other than minimumdocumentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE WPI Section Ch, Week 8908 Derwent Publications Ltd., London, GB; Class B07, AN 89-058487 XP002058833 -& JP 01 011 562 A (NISSHO CORP) , 17 January 1989 see abstract; figures	1-22
A	WO 90 12610 A (THEREX CORP) 1 November 1990 see page 14, line 7 - line 13; figure 2	1
A	EP 0 717 961 A (TARGET THERAPEUTICS INC) 26 June 1996 see the whole document	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publicationdate of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

2

Date of the actual completion of theinternational search	Date of mailing of the international search report
13 March 1998	25/03/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Clarkson, P

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte :onal Application No
PCT/US 97/21693

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9012610 A	01-11-90	US 5045060 A	03-09-91
		AU 5534890 A	16-11-90
		EP 0470189 A	12-02-92
		JP 4504812 T	27-08-92
		US 5147483 A	15-09-92
EP 0717961 A	26-06-96	US 5578074 A	26-11-96
		AU 4069295 A	27-06-96
		CA 2165869 A	23-06-96
		JP 8252324 A	01-10-96